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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,885	09/07/1999	WILLIAM JOHN CURATOLO	PC9824AJTJ	3189

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,885	CURATOLO ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 27, 2003 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bechgaard et al. (EP 0080341) in view of Drug Facts and Comparisons.

Bechgaard teach methods of preparing pharmaceutical oral controlled release multiple-unit compositions comprising a core containing an active therapeutic agent such as an antidepressant coated by a polymeric entity which is substantially resistant to gastric environment, but is erodible under the conditions in the small intestine. See p. 8, lines 20-24. The coating of Bechgaard may be selected from the group consisting of acrylic polymers and copolymers, cellulose acetate esters such as mixed particle esters of cellulose containing phthalate groups etc., and may further contain other suitable excipients such as surfactants, fillers, binders and disintegrants. See claims 1, 8-20. Furthermore the oral controlled release of Bechgaard are coated with a coating that is

selectively eroded in the distal part of the small intestine, and will preferably release at least 90 % of the active substance with in one hour at a pH of 7.5. See p. 14, lines 8-16. The reference also teaches that the controlled release multiple-units formulation techniques aim at a controlled release of active substance reduces and delay the peak plasma concentration without affecting the extent of drug availability, and the frequency of undesirable side-effects may be reduced, and also the dosage frequency may be reduced in order to improve patient compliance. See p. 2, 1st full par. The reference also teaches that the actives that are advantageously formulated according to the invention is a substance which exerts an irritating effect on the gastric mucosa and/or is unstable in acidic environment, and/or are sparingly soluble. See p. 8, lines 4 – 16.

While Bechgaard teaches applying the invention to antidepressant actives, the reference fail to specifically teach a sertraline containing enteric release dosage form.

It is well known in the art that oral pharmaceutical preparations that are associated with upper gastric irritation may be formulated in the form on an enteric coated tablet to minimize GI side effects that are associated with direct GI irritation of such drugs. Further, serotonin reuptake inhibitors such as sertraline have been shown to cause stomatitis, gastritis and about 1 % GI related side effects such as hemorrhagic peptic ulcer. See Facts and Comparison, p. 1574, lines 16-20.

One of ordinary skill in the art would have been motivated at the time of the present invention to modify the teachings of Bechgaard by formulating an enteric coated sertraline composition as motivated by Facts and Comparison because 1) Bechgaard teaches that the enteric coated formulations reduce the GI side effects of a drug and

helps patient compliance, and also suggests the application of the invention to antidepressant; 2) Facts and Comparison teaches that sertraline, an antidepressant, causes GI side effects including stomatitis, gastritis and GI related side effects such as hemorrhagic peptic ulcer. The skilled artisan would have had a reasonable expectation of successfully producing oral dosage forms of sertraline that would require less dosage frequency and provide therapeutic benefits with improved safety. The skilled artisan would have been motivated to further optimize the prior art conditions to achieve a desired rate of drug dissolution or a desired rate of disintegration of the enteric coating by routine experimentation. The methods of treating psychiatric illness comprising administering to a patient in need of such delayed oral preparation would have been also obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-116 of U.S. Patent No. 6,517,866.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of the claims are directed to delayed release sertraline dosage forms and the methods of use thereof.

Response to Arguments

Applicant's arguments filed on February 27, 2003 have been fully considered but they are not persuasive.

Applicants assert that no motivation to formulate enteric coated sertraline composition because sertraline rarely causes GI-related side effects. While applicants rely on Physician's Desk Reference to assert that Zoloft is known to rarely cause gastritis and ulcer, it is noted that the PDR also indicates that 28 % and 4 % of the treated patients suffered nausea and vomiting, respectively. Applicants point out that, in a separate evaluation by the manufacturer, gastritis is said to occur rarely and may not be necessarily drug related. In response, examiner is of the opinion that the significantly high occurrence of nausea and vomiting caused by sertraline would have certainly put a skilled artisan on the notice that the safety of sertraline in GI-related side effects should be improved, and provided a motivation to formulate the drug with

improved safety such as the controlled-release multiple-units formulation as disclosed by in Bechgaard.

Conclusion

No claims are allowed.

This is a continued examination under 37 CFR 1.114. All claims are drawn to the same invention claimed in the earlier prosecution and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier prosecution. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605.

The examiner can normally be reached on Monday through Friday, from 7:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER